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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,951	10/04/2004	Gerardo Perez-Camargo	3714652.00509	3093
29157 K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690	7590 05/13/2010			
EXAMINER				
MAEWALL, SNIGDEHA				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
05/13/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

**Advisory Action  
Before the Filing of an Appeal Brief**

**Application No.**

10/509,951

**Applicant(s)**

PEREZ-CAMARGO ET AL.

**Examiner**

Snigdha Maewall

**Art Unit**

1612

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 08 April 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because:  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.  
NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.

6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 35, 45, 48-52 and 57-64.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_

13. ☐ Other: \_\_\_\_\_.

/Snigdha Maewall/  
Examiner, Art Unit 1612

/Gollamudi S. Kishore/  
Primary Examiner, AU 1612

Continuation of 11, does NOT place the application in condition for allowance because:

Applicants contend that the submitted Declaration under 37 C.F.R. §1.132 demonstrates the unexpected results of administering an edible composition comprising an acidifier, taurine, and fish oil to a cat. As supported by the Declaration, a group of 20 cats with low fat digestibility (i.e., less than 80%) was fed diets to determine if, there was an improvement in fat digestibility in old cats fed different diets containing combinations of pancreatic function promoters, liver function promoters, and intestinal mucosa function promoters, a "wet" diet (Diet A), a "dry" diet, (Diet B).

Applicants further add that the diets in the study contained a pancreatic function promoter (Diet A + citric acid), a liver function promoter (Diet A + taurine), an intestinal mucosa function promoter (Diet A + fish oil in the form of omega 3 oils), and a combination of the promoters (Diet C) were formulated and fed to cats using the procedure similar to that given in Example 1 of the above-identified patent application. The citric acid in the diets was in an amount of approximately 0.1% by weight. The taurine in the diets was in an amount of approximately 0.8% by weight. The fish oil in the diets was in an amount of approximately 3% by weight.

Applicants further add as supported by the Declaration, the control diets (Diet A and Diet B) showed a fat digestibility of about 61% and 63%, respectively, as shown in Figure 1 of the Declaration. There was no significant difference between fat digestibility of a wet diet and a dry diet. This confirms that the digestibility of wet and dry diets is substantially the same and that diet is not a factor in evaluating digestibility. Diet A + citric acid, Diet A + taurine, and Diet A + fish oil showed an increase in fat digestibility of 6.6%, 6.1% and 5.5% respectively when compared to the control diets. However, surprisingly, the combination of the three promoters showed a much more pronounced affect on fat digestibility. The combination (Diet C) showed an increase in fat digestibility of 17.5%.

Applicants state that in old cats with reduced fat digestibility (80%), the presence of a single pancreatic function promoter (acidifier), a single liver function promoter (taurine), or a single intestinal mucosa function promoter (omega 3 oils) improved the level of fat digestibility (around 5.5 to 6.6%). However, none of these diets increased the level of fat digestibility above 80%, the level considered as normal. When the inventors provided the same old cats with a diet that contains a combination of a pancreatic function promoter (acidifier), a liver function promoter (taurine), and an intestinal mucosa function promoter (omega 3 oils), the improvement in the level of fat digestibility is more dramatic (around 17.5%). Only with this diet did the old cats reach a level of fat digestibility that was considered normal (above 80%). This is a dramatic effect; not even in young healthy cats can fat digestibility be 100%. Moreover, no digestive system is 100% efficient (every meal produces some fecal content).

Applicants contend that as supported by the Declaration, the results are surprising and unexpected when the percentage of cats that showed an increase in fat digestibility is analyzed as shown in Figure 2 of the Declaration. The percent of cats that had an improved fat digestibility when administered the promoters in combination was 90%, as compared to the 67% to 75% for the promoters alone. About 20% more cats will have increased fat digestibility if administered a combination or promoters than if administered one of the promoters alone. Thus, one critical discovery is that the number of cats that benefit from a combination of a pancreatic function promoter (acidifier), a liver function promoter (taurine), and an intestinal mucosa function promoter (omega 3 oils) is much greater than the number of cats that benefit from a single promoter. Figure 2 shows that 90% of the cats improved their fat digestibility, versus only 75% when fed a diet with a single pancreatic function promoter (acidifier), 67% with a single liver function promoter (Taurine), or 67% with a single intestinal mucosa function promoter (omega 3 oils).

Applicants arguments are not persuasive with respect to insufficient details in declaration as pointed out below:

First applicants show in figure 2, percent of cats that showed improvement, however no statistical data of percent of lipid absorption is shown in various cats. There is no fat digestion data presented so that comparison of cats with low or high absorption of fat with respect to consuming diet with only citric acid, or taurine or fish oil can be compared with cats who consumed diet with combination of the three ingredients such as citric acid, taurine and fish oil. The graph only shows percent of fat digestibility and percent of cats showing improvement, however, no comparative data for individual cat is shown in terms of lipid absorption.

Additionally, the term fat or lipid is a very broad and generic term which can encompass various forms such as fatty acids since fatty acids are building blocks of lipids, including neutral fat, over 70 different fatty acids have been isolated from various cells and tissues. Fatty acids which are building blocks of lipid may contain saturated and unsaturated bonds, some of the examples can be lauric acid, myristic acid or trans vaccenic acid etc. Similarly fats can be acylglycerols or glycerides or di or triacylglycerides etc., see pages 189-190 of

Biochemistry book by Albert et al.(1970). Applicant claims lipid absorption capacity and provides declaration with fat absorption, therefore in light of the existence of several lipids and fats, it is not clear which specific group of fat or lipid absorption is the applicant referring to especially in the absence of statistical data to show fat absorption as pointed out above.

One aspect of the declaration is that the unexpected results shall commensurate with scope of claims, in the instant case, the unexpected results presented by applicants do not show if unexpected fat digestibility and will also exist with lower limits of taurine and fish oil. Instant claims also do not recite any specific amount for pancreatic function promoter and no specific acid such as citric acid is recited in instant claims, the claims recite acidifier generically. No data is presented to show unexpected results due to other pancreatic function promoters such as any acidifier. As such, the declaration is insufficient to overcome the rejection wherein it discloses taurine and fish oil to promote lipid digestibility.

Applicants also contend that the beneficial effects of the edible composition lead to an increase in fat digestibility in the cat that also correlates to an increase in the absorption capacity of Vitamin E by the cat.

Applicants add that none of the cited references alone or in combination show the amount of liver function promoter to be from 0.1% to about 1% as claimed and the references do not show that composition improves or maintains Vitamin E in a cat as claimed.

Applicants similarly argue that Fuchs reference in combination with other references also do not teach the claimed range of taurine.

Applicants arguments are not persuasive, in response to applicants arguments that the claimed range of taurine is not taught by prior art, it is respectfully pointed out that '999 as discussed in the rejection does teach vitamins in the claimed range which has been described in instant specification as liver function promoter, therefore one of ordinary would have envisaged utilizing another liver function promoter with an expectation to obtain similar results because '619 teaches that bile salts are synthesized in the liver from cholesterol conjugated with taurine and within the gastrointestinal lumen these bile salts play an essential role in lipid absorption and fat transport, see column 22 and 23, lines 63-68 and 15-25. (thus bile salt with taurine plays important role in fat absorption. Similarly, Fuchs also teaches vitamin in 5% amount and in combination with '619 and simpson, would have provided motivation to one of ordinary skill to utilize taurine as liver function promoter and thus improve vitamin E in pets. Besides, as discussed earlier due to insufficient evidence in declaration, the rejections are maintained.